

Docket No. 242993US55CONT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF: Bernhard O. PALSSON, et al.

SERIAL NO: New U.S. Application

FILED: Herewith

FOR: METHODS FOR REGULATING THE SPECIFIC LINEAGES OF CELLS PRODUCED IN A HUMAN HEMATOPOIETIC CELL CULTURE, METHODS FOR ASSAYING THE EFFECT OF SUBSTANCES ON LINEAGE-SPECIFIC CELL PRODUCTION, AND CELL COMPOSITIONS PRODUCED BY THESE CULTURES

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97**

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant(s) wish to disclose the following information.

**REFERENCES**

- ☒ The applicant(s) wish to make of record the references listed on the attached form PTO-1449. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

**RELATED CASES**

- ☐ Attached is a list of applicant's pending application(s) or issued patent(s) which may be related to the present application. A copy of the patent(s), together with a copy of the claims and drawings of the pending application(s) is attached along with PTO 1449.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

**CERTIFICATION**

- ☐ Each item of information contained in this information disclosure statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

**DEPOSIT ACCOUNT**

- ☒ Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.



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|--|----|--|----------|---|-----------------------|------------------------------------|-------------------------------|
| Form PTO 1449<br>(Modified)  |    | U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE   |          | ATTY DOCKET NO.<br>242993US55CONT         |                       | SERIAL NO.<br>NEW U.S. APPLICATION |                               |
| LIST OF REFERENCES CITED BY APPLICANT  |    |  |          | APPLICANT<br>Bernhard O. PALSSON, et al . |                       |                                    |                               |
|  |    |  |          | FILING DATE<br>Herewith                   |                       | GROUP                              |                               |
| <b>U.S. PATENT DOCUMENTS</b>   |    |  |          |   |                       |                                    |                               |
| EXAMINER<br>INITIAL  |    | DOCUMENT<br>NUMBER   | DATE     | NAME                                      | CLASS                 | SUB<br>CLASS                       | FILING DATE<br>IF APPROPRIATE |
|  | AA | 6,326,198  | 12/04/01 | Emerson et al                             |                       |                                    |                               |
|  | AB | 6,299,650  | 10/09/01 | Van Blitterswijk et al                    |                       |                                    |                               |
|  | AC | 5,811,094  | 09/22/98 | Caplan et al                              |                       |                                    |                               |
|  | AD | 5,646,043  | 07/08/97 | Emerson et al                             |                       |                                    |                               |
|  | AE | 4,135,975  | 01/23/79 | Lichtman et al                            |                       |                                    |                               |
|  | AF | 4,514,499  | 04/30/85 | Noll                                      |                       |                                    |                               |
|  | AG | 4,861,714  | 08/29/89 | Dean et al                                |                       |                                    |                               |
|  | AH | 5,032,407  | 07/16/91 | Wagner et al                              |                       |                                    |                               |
|  | AI | 5,605,822  | 02/25/97 | Emerson et al                             |                       |                                    |                               |
|  | AJ | 5,670,351  | 09/23/97 | Emerson et al                             |                       |                                    |                               |
|  | AK | 4,481,946  | 11/13/84 | Altshuler et al                           |                       |                                    |                               |
|  | AL | 4,714,680  | 12/22/87 | Civin                                     |                       |                                    |                               |
|  | AM | 4,889,812  | 12/26/89 | Guinn et al                               |                       |                                    |                               |
|  | AN | 5,032,508  | 07/16/91 | Naughton et al                            |                       |                                    |                               |
| <b>FOREIGN PATENT DOCUMENTS</b>  |    |  |          |   |                       |                                    |                               |
|  |    | DOCUMENT<br>NUMBER   | DATE     | COUNTRY                                   | TRANSLATION<br>YES NO |                                    |                               |
|  | AO | 90/15877A2   | 12/27/90 | WIPO w/Abstract                           |                       |                                    |                               |
|  | AP | 95/06409   | 03/09/95 | WIPO w/Abstract                           |                       |                                    |                               |
|  | AQ | 0 358 506  | 03/14/90 | Europe w/Abstract                         |                       |                                    |                               |
|  | AR | 0 455 482  | 11/06/91 | Europe w/Abstract                         |                       |                                    |                               |
|  | AS | 93/18136   | 09/16/93 | WIPO w/Abstract                           |                       |                                    |                               |
|  | AT | 93/18137   | 09/16/93 | WIPO w/Abstract                           |                       |                                    |                               |
|  | AU |  |          |   |                       |                                    |                               |
|  | AV |  |          |   |                       |                                    |                               |
| <b>OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)</b>   |    |  |          |   |                       |                                    |                               |
|  | AW | M. W. Glacken et al., "Mammalian cell culture: engineering principles and scale-up", Trends in Biotechnology, Vol. 1, No. 4, 1983, PP. 102-108   |          |   |                       |                                    |                               |
|  | AX | Steven A. ROSENBERG et al., "In Vitro Growth of Murine T Cells II. Growth of in Vitro Sensitized Cells Cytotoxic for Alloantigens", The Journal of Immunology, Vol. 121, No. 5. November 1978, PP. 1951-1955 |          |   |                       |                                    |                               |
|  | AY | W. French ANDERSON, "Prospects for Human Gene Therapy", Science, Vol. 26, October 26, 1987, pp. 401-409  |          |   |                       |                                    |                               |
|  | AZ | T.M. Dexter, "The Message in the medium", Nature, Vol. 309, June 1984, pp 746-747  |          |   |                       |                                    |                               |
| Examiner   |    |  |          |   | Date Considered       |                                    |                               |
| *Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. |    |  |          |   |                       |                                    |                               |

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| EXAMINER<br>INITIAL  |    | DOCUMENT<br>NUMBER   | DATE     | NAME                                     | CLASS                 | SUB<br>CLASS                       | FILING DATE<br>IF APPROPRIATE |
|  | BA | 5,945,225  | 08/31/99 | Speith-Herfurth et al                    |                       |                                    |                               |
|  | BB | 5,670,147  | 09/23/97 | Emerson et al                            |                       |                                    |                               |
|  | BC | 5,199,942  | 04/06/93 | Gillis                                   |                       |                                    |                               |
|  | BD | 4,808,611  | 02/28/89 | Cosman                                   |                       |                                    |                               |
|  | BE | 4,963,489  | 10/16/90 | Naughton et al                           |                       |                                    |                               |
|  | BF | 5,061,620  | 10/29/91 | Tsakamoto et al                          |                       |                                    |                               |
|  | BG | 5,922,597  | 07/13/99 | Verfaillie et al                         |                       |                                    |                               |
|  | BH | 5,399,493  | 03/21/95 | Emerson et al                            |                       |                                    |                               |
|  | BI | 4,810,643  | 03/07/89 | Souza                                    |                       |                                    |                               |
|  | BJ | 4,965,204  | 10/23/90 | Civin                                    |                       |                                    |                               |
|  | BK | 5,851,832  | 12/22/98 | Weiss et al                              |                       |                                    |                               |
|  | BL | 5,635,386  | 06/03/97 | Palsson et al                            |                       |                                    |                               |
|  | BM | 4,486,188  | 12/04/84 | Altshuler et al                          |                       |                                    |                               |
|  | BN | 4,847,201  | 07/11/89 | Kaswasaki et al                          |                       |                                    |                               |
| <b>FOREIGN PATENT DOCUMENTS</b>  |    |  |          |  |                       |                                    |                               |
|  |    | DOCUMENT<br>NUMBER   | DATE     | COUNTRY                                  | TRANSLATION<br>YES NO |                                    |                               |
|  | BO |  |          |  |                       |                                    |                               |
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|  | BU |  |          |  |                       |                                    |                               |
|  | BV |  |          |  |                       |                                    |                               |
| <b>OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)</b>   |    |  |          |  |                       |                                    |                               |
|  | BW | Manfred R. Koller, et al. "Expansion of Primitive Human Hematopoietic Progenitors in a Perfusion Bioreactor System with LL-3, LL-6, and Stem Cell Factor", Biotechnology, Vol. 11, March, 1993, pp. 358-363  |          |  |                       |                                    |                               |
|  | BX | Bernhard O. PALSSON et al, "Expansion of Human Bone Marrow Progenitor Cells in a High Cell Density Continuous Perfusion System", Biotechnology, Vol. 11, March, 1993, pp. 368-372  |          |  |                       |                                    |                               |
|  | BY | Giovanni MIGLIACCIO et al., "In Vitro Differentiation of Human Granulocyte/Macrophage and Erythroid Progenitors: Comparative Analysis of the Influence of Recombinant Human Erythropoietin, G-CSF, GM-CSF, and IL-3 in Serum-Supplemented and Serum-Deprived Cultures", Blood, Vol. 72, No. 1 July 1988, pp. 248-255 |          |  |                       |                                    |                               |
|  | BZ | Ian K. McNiece et al., "Studies on the Myeloid Synergistic Factor From 5637: Comparison with Interleukin-1 Alpha", Blood, Vol. 73, No. 4 (March), 1989, pp. 919-923  |          |  |                       |                                    |                               |
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|                     | CA | 5,004,681          | 04/02/91 | Boyse et al   |       |              |                               |
|                     | CB | 5,851,832          | 12/22/98 | Weiss et al   |       |              |                               |
|                     | CC | 6,326,198          | 12/01    | Emerson et al |       |              |                               |
|                     | CD |                    |          |               |       |              |                               |
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## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)

|  |    |   |
|--|----|---|
|  | CW | Paul BAINES et al., Exp. Hematol. 16:785-789 (1988)   |
|  | CX | Jan A. NOLTA et al., Human Gene Therapy, 1:257-268 (1990)   |
|  | CY | John R. STEPHENSON et al., Proc. Nat. Acad. Sci. U.S.A., Vol. 68, No. 7, pp. 1542-1546, July 1971 |
|  | CZ | Giovanni MIGLIACCIO et al., Exp. Hematol. 18:1049-1055 (1990)                                     |

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|  |    |                    |      |         | YES         | NO |
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## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)

|  |    |   |
|--|----|---|
|  | DW | Richard M. Schwartz et al., "In Vitro Myelopoiesis Stimulated by Rapid Medium Exchange and Supplementation With Hematopoietic Growth Factors", Blood, Vol 78, No. 12, December 15, 1991, pp. 3155-3161  |
|  | DX | Rob E. Ploemacher et al., "Use of Limiting-Dilution Type Long-Term Marrow Cultures in Frequency Analysis of Marrow-Repopulating and Spleen Colony-Forming Hematopoietic Stem Cells in the Mouse", Blood, Vol 78, No. 10 (November 15, 1991, pp. 2527-2533 |
|  | DY | Manfred R. Koller et al., "Effects of Synergistic Cytokine Combinations, Low Oxygen, and Irradiated Stroma on the Expansion of Human Cord Blood Progenitors", Blood, Vol 80, No. 2 (July 15, 1992), pp. 403-411   |
|  | DZ | J. AIKEN et al., Journal of Pediatric Surgery, Vol. 25, No. 1 (January), 1990; pp. 140-145  |

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|   | EA |   |      |  |  |                                    |                               |
|   | EB |   |      |  |  |                                    |                               |
|   | EC |   |      |  |  |                                    |                               |
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| <b>OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)</b>  |    |   |      |  |  |                                    |                               |
|   | EW | C. FAVRE et al., "Interleukin-4 has Basophilic and Eosinophilic Cell Growth-Promoting Activity on Cord Blood Cells", Blood, Vol. 1, January 1, 1990, pp. 67-73  |      |  |  |                                    |                               |
|   | EX | Yoichi TAKAUE et al., "Limiting-Dilution Analysis of the Effects of Colony-Stimulating Factors, Phytohemagglutinin, and Hydrocortisone on Hematopoietic Progenitor Cell Growth", Blood, Vol. 70, No. 5, November, 1987, pp. 1611-1618 |      |  |  |                                    |                               |
|   | EY | Yoichi TAKAUE et al., "Effect of Recombinant Human G-CSF, GM-CSF, IL-3, and IL-1 $\alpha$ on the Growth of Purified Human Peripheral Blood Progenitors", Blood, Vol. 76, No. 2, July 15, 1990, pp. 330-335                            |      |  |  |                                    |                               |
|   | EZ | H. J. Sutherland et al., "Alternative Mechanisms With and Without Steel Factor Support Primitive Human Hematopoiesis", Blood, Vol. 81, No. 6, March 15, 1993, pp. 1465-1470   |      |  |  |                                    |                               |
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|                     | FA |                    |      |      |       |              |                               |
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|  | FO |                    |      |         |                       |  |
|  | FP |                    |      |         |                       |  |
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## OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)

|  |    |  |
|--|----|--|
|  | FW | Lucia H. Coutinho et al., "Effects of Recombinant Human Granulocyte Colony-Stimulating Factor (CSF), Human Granulocyte Macrophage-CSF, and Gibbon Interleukin-3 on Hematopoiesis in Human Long-Term Bone Marrow Culture", Blood, Vol. 11, June 1, 1990, pp. 2118-2129  |
|  | FX | Susan C. GUBA et al., "Bone Marrow Stromal Fibroblasts Secrete Interleukin-6 and Granulocyte-Macrophage Colony-Stimulating Factor in the Absence of Inflammatory Stimulation: Demonstration by Serum-Free Bioassay, Enzyme-Linked Immunosorbent Assay, and Reverse Transcriptase Polymerase Chain Reaction", Blood, Vol. 80, No. 5, September 1, 1992, pp. 1190-1198 |
|  | FY | Richard M. SCHWARTZ et al., "Rapid medium perfusion rate significantly increases the productivity and longevity of human bone marrow cultures", Proc. Natl. Acad. Sci. USA, Vol. 88, pp. 6760-6764, August 1991  |
|  | FZ | David E. HARRISON et al., "Primitive hemopoietic stem cells: direct assay of most productive populations by competitive repopulation with simple binomial, correlation and covariance calculations", Experimental Hematology 21:206-219 (1993)   |

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New U.S. Application

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|   | HW | Shiang HUANG et al., "Formation of haematopoietic Microenvironment and haematopoietic stem cells from single human bone marrow stem cells", Nature, Vol. 360, 24/31 December 1992, pp. 745-749 |      |  |                       |                                    |                               |
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|   | TK |   |      |  |                       |                                    |                               |
|   | TL |   |      |  |                       |                                    |                               |
|   | TM |   |      |  |                       |                                    |                               |
|   | TN |   |      |  |                       |                                    |                               |
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|   | TO |   |      |  |                       |                                    |                               |
|   | TP |   |      |  |                       |                                    |                               |
|   | TQ |   |      |  |                       |                                    |                               |
|   | TR |   |      |  |                       |                                    |                               |
|   | TS |   |      |  |                       |                                    |                               |
|   | TT |   |      |  |                       |                                    |                               |
|   | TU |   |      |  |                       |                                    |                               |
|   | TV |   |      |  |                       |                                    |                               |
| <b>OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)</b>  |    |   |      |  |                       |                                    |                               |
|   | TW | Yu-Chung YANG et al., "Human IL-3 (Multi-CSF): Identification by Expression Cloning of a Novel Hematopoietic Growth Factor Related to Murine IL-3", Cell, Vol. 47, pp. 3-10, October 10, 1986 |      |  |                       |                                    |                               |
|   | TX | Dunbar et al., Gene transfer into hematopoietic progenitor and stem cells: Progress and problems. Stem Cells, 12:563-576  |      |  |                       |                                    |                               |
|   | TY | Friedmann et al., Overcoming the obstacles to gene therapy. Sci. Am. pp. 96-101   |      |  |                       |                                    |                               |
|   | TZ | Orkin and Motulsky. Report and recommendations of the panel to assess the NIH investment in research on gene therapy.   |      |  |                       |                                    |                               |
| Examiner  |    |   |      |  | Date Considered       |                                    |                               |
| <small>*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</small> |    |   |      |  |                       |                                    |                               |

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|   | UB |  |      |  |                       |                                    |                               |
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|   | UN |  |      |  |                       |                                    |                               |
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|   | UO |  |      |  |                       |                                    |                               |
|   | UP |  |      |  |                       |                                    |                               |
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|   | UU |  |      |  |                       |                                    |                               |
|   | UV |  |      |  |                       |                                    |                               |
| <b>OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)</b>  |    |  |      |  |                       |                                    |                               |
|   | UW | Verma et al. Gene therapy -promises, problems and prospects. Nature 389:239-242  |      |  |                       |                                    |                               |
|   | UX | Kuby; Clinical Transplantation, 1994, Immunology: 573.   |      |  |                       |                                    |                               |
|   | UY | R. Ian FRESHNEY, "Culture of Animal Cells A Manual of Basic Technique", (1987) Department of Medical Oncology Cancer Research Campaign Laboratories University of Glasgow, Second Addition, pp. 305-307, Alan R. Liss, Inc. (New York) |      |  |                       |                                    |                               |
|   | UZ |  |      |  |                       |                                    |                               |
| Examiner  |    |  |      |  | Date Considered       |                                    |                               |
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